NISTIR 5428

# Program Handbook

# Requirements for Obtaining NIST Approval/Recognition of a Laboratory Accreditation Body Under P.L. 101-592 The Fastener Quality Act

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**TECHNOLOGY ADMINISTRATION**
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**NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY**
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## 1.0 INTRODUCTION

On November 16, 1990 the United States Congress enacted the Fastener Quality Act, P.L. 101-592 (The Act). The Act requires the establishment of procedures and conditions for the accreditation of laboratories engaged in the inspection and testing of certain fasteners entered into commerce within the United States.

The Act stipulates that all fasteners to which it applies shall be tested by a laboratory which has been accredited either by the National Institute of Standards and Technology (NIST) or by a NIST approved/recognized accreditation body.

This document describes the NIST process in fulfilling its obligations to evaluate accreditation bodies as required by section 6 of the Act.

Section 6(a)(1)B requires the establishment of procedures under which private entities may apply for approval to engage directly in the accreditation of laboratories.

Section 6(a)(1)C requires the establishment of procedures under which foreign laboratories accredited by their governments or other organizations can be deemed to satisfy the laboratory accreditation requirements of the act.

The text of this handbook provides specific NIST interpretations of the general requirements published at 15 CFR Part 280 "Procedures for Implementation of the Fastener Quality Act" (The Procedures) subparts B,D,E and F. This handbook explains the procedures, conditions, and requirements for gaining NIST approval/recognition.

For full understanding of all requirements, interested parties are advised to read "The Procedures" in entirety. In addition to the laboratory accreditation requirements, many other important issues are contained in that document.

NIST invites users to provide comments or suggestions for modification, clarification or improvement of this document or any of the requirements.

<u>All participants should be aware that the Act contains provisions for assessing civil penalties as great as $25,000 for certain violations.</u>

## 1.1 Definitions

For the purposes of this handbook the following definitions are used:

### 1.2.1 Accreditation Body, Applicant, Participant

The entity which requests evaluation or is being evaluated for NIST recognition to accredit fastener testing laboratories.

### 1.2.2 Fastener Testing Accreditation Program

The specific activity of an accreditation body which evaluates and accredits laboratories which provide testing services for fasteners or fastener materials.

### 1.2.3 Accredited Laboratory List

A list compiled and maintained by NIST of all laboratories which have been accredited by NIST or any NIST recognized accreditor in accordance with the requirements of The Act.

### 1.2.4 Approved/Recognized Accreditation Body List

A list of all accreditation bodies which have been evaluated and approved/recognized by NIST in accordance with the requirements of The Act.

### 1.2.5 Authorized Representative (of an applicant organization)

An individual with the authority to make binding commitments on behalf of an applicant. The authorized representative will be the person who will be responsible for all communication with NIST and who will ensure that the applicant complies with all NIST program requirements.

### 1.2.6 NIST Recognition

For purposes of this document, the term "recognition" is used to mean either "approval" or "recognition" with the understanding that otherwise "approval" is the usual term for designating acceptable private bodies and "recognition" is the usual term for indicating foreign government bodies with whom an agreement has been negotiated.

NIST recognition under this program is limited to accreditation bodies that accredit laboratories which perform testing on materials or products covered under The Act. Such testing may include chemical analysis, mechanical and physical testing and inspection, metallography, or dimensional inspection.

## 2.0 REQUESTING EVALUATION

The method of initiating a request for NIST evaluation is dependent upon the type of accreditation body.

### 2.1 Foreign Governments

An accreditation system operated by a foreign government should submit a letter to the Director, Office of Standards Services, NIST - Admin A603, Gaithersburg, MD 20899 indicating its interest in obtaining U.S. Government recognition for an accreditation body under the Fastener Quality Act. Subsequent correspondence will include explicit instructions on how to proceed.

### 2.2 Private Bodies

Private sector accreditation bodies, whether foreign or domestic, must submit an application to NIST. All forms must be completed in English and must provide sufficient information and detail to fully describe the fastener testing laboratory accreditation program. The applicant may include any enclosures or attachments appropriate to describe applicable capabilities or resources.

An application may be amended at any time prior to a final decision. However, dependent upon the nature of changes, additional time or fees may be required to evaluate those changes.

An application may be withdrawn at any time prior to a final decision. If an application is withdrawn, the entity may later reapply.

## 3.0 COST REIMBURSEMENT

### 3.1 Evaluation Costs

The Program is operated on a cost reimbursable basis; that is, all participants must reimburse NIST for the costs of conducting an evaluation. The total cost will depend on the number of sites to be visited, location(s), extent of operations, scope of recognition sought, and/or overall amount of time required to complete the assessment.

Additional charges will be made for any supplementary activities performed by NIST, e.g. additional on-site visits, extensive re-evaluations of materials resulting from a large number of deficiencies, or the cost of obtaining needed interpreters.

### 3.2 Laboratory Listing Fee

An accreditation body shall collect and forward to NIST an annual listing fee for each laboratory which is to be included on the Accredited Laboratory List.

## 4.0 EVALUATION PROCESS

The process of evaluating an organization consists of a number of activities which take place prior to recognition being granted and continuously thereafter. Recognition is preceded by initial review of the application, quality system review and evaluation, on-site assessment, participant response to the assessment report, laboratory visits, and final evaluation and decision. After recognition is granted surveillance activities and periodic on-site assessment visits are conducted.

### 4.1 Initial Review

Each initial request for evaluation is reviewed to: (1) determine that all required information is included, (2) determine whether the entity is eligible for further evaluation, and (3) develop an estimated cost. If an entity is deemed to be ineligible all submitted information will be returned with an explanation of the ineligibility.

### 4.2 Quality System Review and Evaluation

Each participant must submit copies of its quality documentation for review and evaluation. This material is reviewed to evaluate whether it describes a quality system that promotes an adequate quality level of performance and management. During this phase, NIST may need to interact with the organization for clarification of certain items or to request additional information.

Quality documentation submitted for review need not be in English. However, if an interpreter or translator is required the organization is billed for the expense incurred.

If it is not possible for a participant to submit quality documentation in advance the review can be performed during the on-site assessment. Should this occur, extra time and expense may be required.

### 4.3 On-site Assessment

An on-site assessment of each participant's facilities is conducted prior to initial recognition and every other year thereafter until the recognition is terminated. The assessment encompass's physical inspection of the technical and administrative facilities and practices and covers all sites involved in the accreditation of fastener testing laboratories. An assessment team comprised of a NIST staff member and one or more appropriate technical experts conduct the assessment.

Prior to a regularly scheduled visit, a participant is informed of the identity of the assessment team and has the right to appeal the selection. Such appeal must be received in writing at least 20 working days prior to the scheduled date of the visit and must provide a substantive reason in order for a change to be made.

If the personnel of the organization being evaluated normally speak (and documentation is written in) a language other than English, NIST will arrange for an interpreter to accompany the assessment team; the cost will be billed to the participant.

The normal sequence of an on-site assessment is:

4.3.1 Entrance Meeting

Upon arrival at the participant's facility, the assessment team meets with Management to discuss what is to be accomplished and agree on a plan of action. The meeting allows all parties to become acquainted and give the assessment team the opportunity to understand the management structure. It is recommended that a staff member be designated as the main contact person to assist the assessment team.

4.3.2 Walk Thru and Staff Introductions

The assessment team briefly tours the facilities to familiarize themselves with the layout and which staff members are responsible for the areas of interest.

4.3.3 Assessment

All phases of the operation pertaining to the scope of the request for evaluation are reviewed. A checklist is used to guide the review and to ensure uniformity of assessment from one organization to another. The assessors review relevant documents, review files, observe specific operations, and interview staff members.

The assessment focuses on ascertaining that the actual operation of the organization is the same as described in the quality documentation. All procedures involved in the accreditation process are reviewed.

Personnel representing the following must be made available for interview by the assessment team:

management personnel

persons who make accreditation decisions

laboratory assessors

clerical and support personnel

technical project managers

quality assurance

The assessment team also observes and evaluates:

information and reporting systems, data base systems;

all files, records, documents relating to accreditation procedures, policies, and activities;

assessment reports of selected laboratories;

selected final evaluation reports on which accreditation were based;

appeals and complaints regarding the accreditation body or laboratories;

assessor qualification, training, competency records.

The assessment team must have freedom of movement and access to all persons and information relating to the request for evaluation. The assessment team treats all information and conversations as confidential. No information is disclosed except as may be required by law.

The assessment team may be required to review information considered proprietary. All such information is treated accordingly. Refusal to allow review of such materials may result in denial of recognition.

4.3.4 Development of On-Site Assessment Report

The assessment team develops a draft report containing a comprehensive review of the team's impressions on both the strengths and weaknesses of the participant. Any deficiencies requiring resolution are clearly identified.

4.3.5 Exit Meeting

Once the assessment team is satisfied that it has completed its task at the site and developed a draft report, a meeting is arranged to discuss the findings with management. At the conclusion of this meeting the Authorized Representative of the organization must sign the draft report, thereby acknowledging the discussions, and the responsibility to respond, in the allotted time, to any deficiencies identified.

## 4.4 Final Report

NIST staff prepares a final report from the draft report and forward it to the participant within 10 working days after the assessment. In most cases the final report is essentially the same as the draft report unless additional information has been uncovered or there were issues that required clarification.

The final report is normally the final vehicle to present the definitive assessment findings. However, in some cases additional information may surface with significant bearing on the evaluation, and a supplementary report may be necessary. Any supplementary report including required actions is promptly forwarded to the participant.

## 4.5 Participant Response To Assessment Report

The participant must respond to all identified deficiencies in writing to NIST. Specific corrective actions taken or the proposed plans to resolve each deficiency must be described. Plans must include specific actions, time frames, dates, etc. Supporting materials may be necessary, e.g., invoice, a written procedure, etc. In some cases, an additional on-site visit, at additional cost, may be necessary to observe stated resolutions.

New applicants are generally expected to resolve deficiencies within 90 days. NIST must be informed if additional time is required. If the evaluation process takes longer than one year, additional administrative costs may be incurred.

Organizations holding a current valid NIST recognition must resolve all deficiencies within 30 days of receipt of the final report or recognition will be suspended until full conformance is demonstrated.

## 4.6 Laboratory Visits

As part of the evaluation process of an accreditation body, NIST assessors will accompany assessors from the accreditation body during one or more laboratory on-site assessments.

NIST will negotiate with the accreditation body the number and identity of the laboratories to be visited and the accreditation body must pay all associated costs.

## 4.7 Final Evaluation and Decision

Upon completion of all assessment activities, NIST convenes an evaluation panel to conduct a final evaluation of all information collected regarding an applicant and makes a decision on the appropriate action. (See 5.0 Program Actions)

The decision is based on the review and evaluation of all materials submitted by the organization, reports covering the quality system review, on-site assessment(s), laboratory visits, and deficiency resolution.

### 4.8 Surveillance

NIST may, at its discretion, whether or not for cause, conduct a full or partial on-site visit or other forms of surveillance of a recognized body or any of the laboratories accredited by that body to observe or verify conformance with program requirements.

## 5.0 PROGRAM ACTIONS

NIST may grant, deny, suspend, or terminate recognition.

### 5.1 Granting Approval/Recognition

If an organization demonstrates conformance with all requirements, NIST grants it recognition as having demonstrated the ability to evaluate testing laboratories and publicly attest to qualified laboratories competence through accreditation.

The organization is provided with documentation stating the terms and conditions of the recognition, dates of the recognition period, and the specific Scope of Activities for which recognition is granted.

### 5.2 Denial

Recognition will be denied if an organization fails to demonstrate conformance. NIST notifies the organization in writing of its intention to deny and the reason(s) therefore. An organization is given 90 days to resolve any deficiencies which form the basis of the proposed denial. Unless resolution is achieved in that time the organization is denied recognition.

An organization may appeal a denial to the NIST Director by submitting a statement of reasons why recognition should not be denied. The Director evaluates the appeal and informs the organization in writing of a final decision within 60 days following receipt of the appeal. The organization may re-submit a request for evaluation when it believes that it can demonstrate conformance.

### 5.3 Suspension

If it is determined that a recognized body temporarily cannot demonstrate conformance, e.g., a deficiency is uncovered during surveillance or the body has changed ownership, recognition may be suspended until full conformance has been demonstrated.

If recognition is suspended, the accreditation body may not grant any additional accreditation under The Act, nor conduct any evaluation activities covered by the recognition. The accreditation body must, within 5 days, inform all laboratories accredited under The Act of the suspension.

The written notice shall state the effective date of the suspension and inform the laboratories that NIST will normally NOT suspend or remove them from the accredited laboratory list, unless they contributed to the conditions which led to the suspension or in NIST's judgement removal is justified.

### 5.4 Termination

Termination may be voluntary or involuntary.

#### 5.4.1 Voluntary Termination

An accreditation body may at any time voluntarily terminate its participation in the program by giving written notice to NIST and all laboratories accredited under that program.

#### 5.4.2 Involuntary Termination

NIST may terminate, fully or partially, the recognition of an accreditation program whenever it deems such an action to be in the public interest. Such an action may result if the accreditation body engages in illegal activity or fraud, is unable to meet NIST requirements or exhibits other factors detrimental to producing an acceptable laboratory accreditation program.

#### 5.4.3 Termination Procedures

NIST notifies the accreditation body in writing of the intent to terminate the recognition and the reason(s) therefore. The notice states that recognition is suspended as of the date of the notice, and that the body may not grant any additional accreditation under The Act, or conduct any evaluation activities covered by the recognition.

The accreditation body is given the opportunity to respond to, rebut or correct any deficiencies which form the basis of the proposed termination. If the basis for the termination is not reconciled within 30 days, or such longer time as NIST may allow, the termination becomes effective.

The body may appeal to the NIST Director by submitting a statement of reasons why the recognition should not be terminated. NIST may, at its discretion, delay implementing the termination action pending a final decision by the Director. If recognition is terminated, the accreditation body may not state nor imply that it has NIST recognition, nor may it grant any accreditation under the NIST recognition.

The terminated body shall send a written notice to all client laboratories informing them of that termination and the effective date. The notice shall inform the laboratories that NIST will normally NOT remove them from the approved laboratory list unless they contributed to the conditions which led to the termination or in NIST's judgement removal is justified. They shall be advised that, if they want to continue testing under The Act, they should expeditiously seek accreditation from NVLAP or another NIST recognized fastener testing laboratory accreditation program.

Laboratories previously accredited by a terminated accreditation body are allowed a specified period of time in which to acquire accreditation under NVLAP or another NIST recognized fastener testing laboratory accreditation program to avoid removal from the accredited laboratory list. (See appendix C)

An accreditation body whose recognition has been terminated may submit a request for re-evaluation when it believes that it can demonstrate conformance.

## 5.5 Participant Options in Response to an Adverse Action

If NIST proposes to deny, suspend, or terminate recognition, and the organization has been so notified in writing, citing the specific reasons or elements of nonconformance with the requirements, an organization may choose to:

Appeal the decision requesting that recognition be granted or continued and providing appropriate justification.

Submit additional information for further evaluation. If an additional on-site visit is required, additional fees may be required.

Accept the decision.

## 5.6 Appeal

An organization may appeal any action taken against it.

All appeals must be in writing and include complete documentation setting forth the appellant's position. The appeal of an action must be filed within 30 days.

Appeals should be sent to:

Director, NIST, Gaithersburg, MD 20899

The accreditation body will be informed of the decision within 60 days following receipt of the appeal.

## 6.0 OBLIGATIONS OF A RECOGNIZED BODY

### 6.1 Continuous Conformance

It shall be incumbent upon each body operating a recognized fastener testing laboratory accreditation program to conform with all NIST requirements throughout the period of participation. Failure to maintain conformance is cause for termination of recognition.

NIST routinely performs a complete on-site assessment of each recognized accreditation body every two years. Other types of surveillance are conducted at least annually to ensure continued conformance.

Upon request, an accreditation body shall make available to NIST, any document, information, or material related to the recognized accreditation activities.

### 6.2 Proper Use of Accredited Status and Claims

Neither a recognized accreditation body, nor any laboratory accredited under The Act, shall take any action which constitutes or implies certification, approval, or endorsement by NIST or any other agency of the U.S. government of fasteners entered into commerce in the United States.

Neither a recognized accreditation body, nor any laboratory accredited under The Act, shall take any action which constitutes or implies that the accreditation body or an accredited laboratory is recognized by NIST for any testing or other activities beyond which are specifically stated in the NIST recognition documents.

### 6.3 Keeping NIST informed

#### 6.3.1 Organizational Changes

An approved/recognized accreditation body must inform NIST within 30 days of any major change in any factors which might affect its ability to operate, such as replacement of personnel (e.g., the Executive, key supervisors, and accreditation decisionmakers); any major change in procedure, policymaking or direction; or change in location, ownership, or business affiliations. Failure to provide timely and accurate information may result in termination of recognition.

#### 6.3.2 Accredited Laboratory Status

NIST maintains a list of all fastener testing laboratories accredited by all NIST recognized accreditation bodies. Listed laboratories are the only ones legally eligible to issue test reports concerning fasteners or materials which come under The Act. (See appendix C)

Each recognized accreditation program must keep NIST informed of all accreditation actions taken concerning fastener testing laboratories on the accredited laboratory list. This information is vital for maintaining an up to date list. All new accreditation, renewals, denials, terminations, revocations, suspensions, changes in scope (additions or deletions), must be reported to NIST within 5 working days.

The following information must be included:

Name of Laboratory
Address (Country, state, city, zip code)
Telephone/Fax numbers
Authorized Representative
Names of all Approved Signatories
Accreditation Status/Change
Scope of accreditation/change
Effective Dates of Accreditation status/change

### 6.3.3 Approved/Recognized Accreditation Body List

NIST maintains a list of the names and pertinent information on all approved/recognized accreditation bodies which have been deemed to comply with the requirements of the FQA (Public Law 101-592). Only listed accreditation bodies are eligible to issue legally complying accreditation to laboratories to test fasteners under the FQA. (See Appendix C)

An accreditation body must maintain compliance with all of the conditions and requirements in order to retain its listing.

All lists are maintained on an electronic database and entries are updated as information becomes available. Hard copies are available on a limited special request basis via mail or telefax. Telephone requests about listings are honored and answered as conditions permit.

## 7.0 ACCREDITATION BODY REQUIREMENTS

Accreditation bodies shall be able to demonstrate conformance to the requirements of 15 CFR Part 280 - Subpart F - Requirements for Fastener Laboratory Accreditation Bodies. These requirements are based on ISO Guide 58 - "Calibration and Testing Laboratory Accreditation Systems - General Requirements for Operation and Recognition".

NIST assesses conformance to these requirements by evaluating the quality documentation submitted and by on-site assessment. Subpart F is printed below, with specific NIST interpretations of the general statements as indicated in **bold print.**

## Subpart F - Requirements for Fastener Laboratory Accreditation Bodies

Sec. 280.500 Introduction.

This subpart sets out organizational, operational and other requirements that must be met by all accreditation bodies approved or recognized (hereafter "approved/recognized") by NIST under Subparts D or E. This subpart also sets out the requirements against which an approved/recognized accreditation body assesses the technical competence of an applicant testing laboratory. These requirements include conditions with respect to Subpart C of these regulations.

Sec. 280.501 Accreditation Body.

(a) General provisions

(1) The procedures under which an approved/recognized accreditation body operates shall be administered in a non-discriminatory manner.

Access to an accreditation system operated by an approved/recognized accreditation body shall not be conditional upon the size of the laboratory or membership in any association or group, nor shall there be undue financial conditions to restrict participation.

(2) The competence of an applicant laboratory shall be assessed by an approved/recognized accreditation body against requirements consistent with the conditions set out in Subpart C of these regulations.

(3) The requirements of 280.501(a)(2) may have to be interpreted for a specific test or type of test by an approved/recognized accreditation body. These interpretations shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence. They shall be published by the accreditation body.

(4) An approved/recognized accreditation body shall require accredited laboratories to maintain impartiality and integrity.

(5) An approved/recognized accreditation body shall confine its requirements, assessment and decision on accreditation to those matters specifically related to the scope of the accreditation being considered.

(b) Organization of an approved/recognized accreditation body

(1) An approved/recognized accreditation body shall:

A) be a legally identifiable, public or private entity;

B) have rights and responsibilities relevant to its accreditation activities;

C) have adequate arrangements to cover liabilities arising from its operations and/or activities.

D) have the financial stability and resources required for the operation of an accreditation system;

E) have and make available on request a description of the means by which it receives its financial support;

F) employ a sufficient number of personnel having the necessary education, training, technical knowledge and experience for handling the type, range and volume of work performed, under a senior executive who is responsible to the organization, body or board to which it reports;

**The senior executive shall have sufficient experience and demonstrated ability in the successful operation of an accreditation program operating on a national or international scale.**

**The executive shall have appropriate experience or educational background in management principles and application, general technical knowledge, and personnel management.**

**There shall be at least one staff member who has technical expertise in engineering, physics, metallurgy, or other technical field which provides enough technical background to understand the technology involved with testing fasteners.**

G) have a quality system including an organizational structure, that enables it to give confidence in its ability to operate a laboratory accreditation system satisfactorily;

H) have documented policies and procedures for the operation of the quality system that include:

- policies and decision-making procedures that distinguish between laboratory accreditation and any other activities in which the body is engaged;

- policies and procedures for the resolution of complaints and appeals received from laboratories about the handling of accreditation matters, or from users of services about accredited laboratories or any other matters;

I) together with its senior executive, and staff, be free from any commercial, financial and other pressures which might influence the results of the accreditation process;

J) have formal rules and structures for the appointment and operation of committees involved in the accreditation process;

such committees shall be free from any commercial, financial and other pressures that might influence decisions or shall have a structure where members are chosen to provide impartiality through a balance of interest where no single interest predominates;

**The persons who review and decide whether to grant or deny accreditation to a laboratory shall be technically qualified to make such decisions. These persons shall have sufficient demonstrated experience in the evaluation of technical programs. They shall not be laboratory owners or operators, nor be in a situation where their decision(s) might have a prejudicial impact to the granting or denying an accreditation.**

K) establish one or more technical committees, each responsible, within its scope, for advising the accreditation body on the technical matters relating to the operation of its accreditation system;

**An accreditation body shall have access to appropriate experts, professional services or resources that can be used for technical support, advice and assistance.**

L) not offer consultancies or other services which may compromise the objectivity of its accreditation process and decisions;

M) have arrangements that are consistent with applicable laws, to safeguard, at all levels of its organization (including committees), confidentiality of the information obtained relating to applications, assessment and accreditation of laboratories;

(2) An approved/recognized accreditation body shall have arrangements for controlling the ownership, use and display of the accreditation documents and controlling the manner in which an accredited laboratory may refer to its accredited status.

(c) Quality system

(1) An approved/recognized accreditation body shall operate a quality system appropriate to the type, range and volume of work performed. This system shall be documented and the documentation shall be available for use by the accreditation body staff. The accreditation body shall designate a person having direct access to its highest executive level, to take responsibility for the quality system and the maintenance of the quality documentation.

(2) The quality system shall be documented in a quality manual and associated quality procedures, and the quality manual shall contain or refer to at least the following;

A) a quality policy statement;

B) the organizational structure of the accreditation body;

C) the operational and functional duties and services pertaining to quality, so that each person concerned will know the extent and the limits of their responsibility;

D) administrative procedures including document control;

E) policies and procedures to implement the accreditation process;

F) arrangements for feedback and corrective actions whenever discrepancies are detected;

G) the policy and procedures for dealing with appeals, complaints and disputes;

H) the policy and procedures for conducting internal audits;

I) the policy and the procedures for conducting quality system reviews;

J) the policy and the procedures for the recruitment and training of assessors and monitoring their performance.

**NIST reviews the quality documentation to evaluate whether it contains up-to-date, complete, and detailed information describing the accreditation body and the internal organization and quality system used to control the quality of all accreditation activities. The documentation should contain policies, procedures and methods to cover all aspects of the operation to ensure that the managerial, technical, administrative and human factors elements which might affect the quality of services are under control. Guidance in developing or operating a quality system can be found in ISO/IEC Guides 9004 and 9004-2 (see References).**

**The following shall be included:**

**primary functions;**

**organizational chart defining relevant relationships;**

**technical resources, including facilities, equipment;**

**scope of operation;**

**management personnel;**

**quality objectives;**

**the accreditation criteria (requirements) that laboratories must satisfy in order to be granted accreditation;**

the function and location of each unit which is involved in fastener testing laboratory accreditation activities;

copies of program handbooks, or other explanatory documents;

examples of all forms used e.g., applications for accreditation, control forms, proficiency test enrollment and data sheets, assessment checklists, report forms, etc.

The following policies and procedures shall be included to describe how the accreditation body:

adjudicates all matters relating to its operation;

reviews policies;

reviews finances;

conducts staff training;

creates committees as required;

provides comment by affected entities;

controls the ownership, use and display of the accreditation documents, and the manner in which an accredited laboratory may refer to its accreditation status;

maintains control over information collection and handling, e.g. laboratory status, scheduling of renewals, on-sites, assessor assignments, proficiency testing etc.;

determines applicant eligibility;

conducts the laboratory on-site assessment, including criteria for assessment, checklists, report forms and requirements.

conduct and evaluate proficiency testing;

makes decisions on accreditation actions, e.g.,accreditation, renewal, revocation, suspension, denial, termination;

allows laboratories to refer to their accredited status on test reports;

prevents laboratory accreditation from being misrepresented as product certification;

ensures that accredited laboratories do not imply product certification, approval or endorsement by NIST or any other agency of the federal government as a result of being accredited;

**controls or avoid conflicts of interest by staff, assessors, any committee members or contractors utilized;**

**handles complaints, e.g. from laboratories, laboratory clients, regulatory agencies, etc.;**

**controls accredited laboratories subcontracting testing services;**

**provides surveillance of accredited laboratories;**

**controls information dissemination, including confidentiality requirements, e.g., directory, RBBS, publicity, phone calls; permits the prompt notification to interested parties of any change in the status of an accredited laboratory;**

**maintains and retains records; and**

**reviews and updates the quality system;**

(3) An approved/recognized accreditation body shall audit its activities to verify that they comply with the requirements of the quality system. The quality system shall be reviewed to ensure its continued effectiveness. Audits and reviews shall be carried out systematically and periodically and recorded together with details of any corrective actions taken.

**NIST requires the quality system to be reviewed at least annually.**

(4) An approved/recognized accreditation body shall maintain records to demonstrate that accreditation procedures have been effectively fulfilled, particularly with respect to application forms, assessment reports, and reports relating to granting, maintaining, extending, suspending or withdrawing accreditation. These accreditation documents shall form part of the record.

(5) An approved/recognized accreditation body shall have a policy and procedures for retaining records. The records shall be retained for a period of at least 10 years, and shall be available to NIST personnel and other persons considered by the accreditation body to have a right of access to these records.

(d) Granting, maintaining, extending, suspending, and withdrawing accreditation

**Accreditation shall not be granted for a period greater than three (3) years.**

(1) An approved/recognized accreditation body shall specify the conditions for granting, maintaining and extending accreditation and the conditions under which accreditation may be suspended or withdrawn, partially or in total for all or part of the laboratory's scope of accreditation.

(2) An approved/recognized accreditation body shall have arrangements to grant, maintain, suspend or withdraw accreditation, increase or reduce the scope of accreditation or require reassessment, in the event of changes affecting the laboratory's activity and operation, such as changes in personnel or equipment, or if analysis of a complaint or any other information indicates that the laboratory no longer complies with the requirements of the accreditation body.

(3) An approved/recognized accreditation body shall have arrangements relating to the transfer of accreditation when the legal status (e.g. ownership) of the accredited laboratory changes.

(e) Documentation

An approved/recognized accreditation body shall provide (through publications, electronic media or other means), update at adequate intervals, and make available on request

1) information about the authority under which accreditation systems operated by the accreditation body were established and specifying whether they are mandatory or voluntary;

2) a document containing the requirements for accreditation in accordance with this document;

3) a document stating the arrangements for granting, maintaining, extending, suspending and withdrawing accreditation;

4) information about the assessment and accreditation process;

5) general information on the fees charged to applicant and accredited laboratories;

6) a description of the rights and duties of accredited laboratories as specified in Section 280.504 this part, including requirements, restrictions or limitations on the use of the accrediting body's logo and on the ways of referring to the accreditation granted.

Sec. 280.502 Laboratory assessors

(a) Requirements for assessors

The assessor or assessment team appointed to assess a laboratory shall:
(1) be familiar with the relevant legal regulations, accreditation procedures and accreditation requirements,

**NIST requires knowledge of the following:**

**the FQA (P.L. 101-592);**

**the appropriate sections of the FQA regulations,**

**the specific technical requirements of the fastener accreditation program; and**

**technical aspects of the specific fastener tests or types of test for which accreditation is sought and, where relevant, with the associated sampling procedures;**

(2) have a thorough knowledge of the relevant assessment method and assessment documents;

(3) have appropriate technical knowledge of the specific tests or types of tests for which accreditation is sought and, where relevant, with the associated sampling procedures;

(4) be able to communicate effectively, both in writing and orally;

(5) be free of any commercial, financial or other pressures or conflicts of interest that might cause assessor(s) to act in other than an impartial or non-discriminatory manner;

(6) not have offered consultancies to laboratories which might compromise their impartiality in the accreditation process and decisions.

(b) Qualification procedures for assessors

An approved/recognized accreditation body shall have an adequate procedure for:

(1) qualifying assessors, comprising an assessment of their competence and training, and attendance at one or more actual assessments with a qualified assessor.

**The accreditation body shall have documented selection criteria that each potential assessor must meet.**

**The criteria shall contain requirements for educational, technical, quality systems, management, and communications skills, with a specified minimum number of years of applicable experience for each category.**

(2) monitoring the performance of assessors.

(c) Contracting of assessors

An approved/recognized accreditation body shall require the assessors to sign a contract or other document by which they commit themselves to comply with the rules defined by the accreditation body, including those relating to confidentiality and those relating to independence from commercial and other interests, and

any prior association with laboratories to be assessed.

(d) Assessor records

An approved/recognized accreditation body shall possess and maintain up-to-date records on assessors consisting of:

(1) name and address;

(2) organization affiliation and position held;

(3) educational qualification and professional status;

(4) work experience;

(5) training in quality assurance, assessment and calibration and testing;

(6) experience in laboratory assessment, together with field of competence;

(7) date of most recent updating of record.

(e) Procedures for assessors

Assessors shall be provided with an up-to-date set of procedures giving assessment instructions and all relevant information on accreditation arrangements.

Sec. 280.503 Accreditation process

(a) Application for accreditation

(1) A detailed description of the assessment and accreditation procedure, the documents containing the requirements for accreditation and documents describing the rights and duties of accredited laboratories (including fees to be paid by applicant and accredited laboratories) shall be maintained up-to-date and given to applicant laboratories.

(2) Additional relevant information shall be provided to applicant laboratories on request.

(3) A duly authorized representative of the applicant laboratory shall be required to sign an official application form, in which or attached to which

A) the scope of the desired accreditation is clearly defined;

B) the applicant's representative agrees to fulfill the accreditation procedure, especially to receive the assessment team, to pay the fees charged to the applicant laboratory whatever the result of the assessment may be, and to accept the charges of subsequent maintenance of the accreditation of the laboratory;

C) the applicant agrees to comply with the requirements for accreditation and to supply any information needed for the evaluation of the laboratory.

(4) The following minimum information shall be provided by the applicant laboratory prior to the on-site assessment:

A) the general features of the applicant laboratory (corporate entity: name, address, legal status, human and technical resources);

B) general information concerning the laboratory covered by the application, such as primary function, relationship in a larger corporate entity and, If applicable, physical location of laboratories involved;

C) a definition of the materials or products tested, the methods used and the tests performed;

D) a copy of the laboratory's quality manual and, where required, the associated documentation.

The information gathered shall be used for the preparation of on-site assessment and shall be treated with appropriate confidentiality.

(b) Assessment

(1) An approved/recognized accreditation body shall appoint qualified assessor(s) to evaluate all material collected from the applicant and to conduct the assessment on its behalf at the laboratory and any other sites where activities to be covered by the accreditation are performed.

(2) To ensure that a comprehensive and correct assessment is carried out, each assessor shall be provided with the appropriate working documents.

(3) The date of assessment shall be mutually agreed with the applicant laboratory. The latter shall be informed of the name(s) of the qualified assessor(s) nominated to carry out the assessment, with sufficient notice so that the laboratory is given an opportunity to appeal against the appointment of any particular assessor.

(4) The assessor(s) shall be formally appointed. A lead assessor shall be appointed, if relevant. The mandate given to the assessor(s) shall be clearly defined and made known to the applicant laboratory.

(c) Sub-contracting of assessment

(1) If an approved/recognized accreditation body decides to delegate fully or partially the assessment of a laboratory to another body, then the accreditation body shall take full responsibility for such an assessment made on its behalf.

(2) An approved/recognized accreditation body shall ensure that the party to which assessment has been delegated is approved/recognized by NIST. **The accreditation body shall inform NIST in writing prior to taking such action.**

(d) Assessment report

(1) An approved/recognized accreditation body may adopt reporting procedures that suit its needs but as a minimum these procedures shall ensure that:

A) a meeting takes place between the assessor or assessment team and the laboratory management prior to leaving the laboratory at which the assessment team provides a written or oral report on the compliance of the applicant laboratory with the accreditation requirements;

B) the assessor or assessment team provides the accreditation body with a detailed assessment report containing all relevant information concerning the ability of the applicant laboratory to comply with all of the accreditation requirements, including any which may come about from the results of proficiency testing;

C) a report on the outcome of the assessment is promptly brought to the applicant laboratory's notice by the accreditation body, identifying any non-compliances that have to be discharged in order to comply with all of the accreditation requirements. The laboratory shall be invited to present its comments on this report and to describe the specific actions taken, or planned to be taken within a defined time, to remedy any non-compliances with the accreditation requirements, identified during the assessment.

(2) The final report authorized by an approved/recognized accreditation body and submitted to the laboratory, if it is different, shall include as a minimum:

A) date(s) of assessment(s);

B) the names of the person(s) responsible for the report;

C) the names and addresses of all the laboratory sites assessed;

D) the assessed scope of accreditation or reference thereto;

E) comments of the assessor(s) or assessment team on the compliance of the applicant laboratory with the accreditation requirements.

(3) The report shall take into consideration:

A) the technical qualification, experience and authority of the staff encountered, especially the persons responsible for the technical validity of test reports or test certificates;

B) the adequacy of the internal organization and procedures adopted by the applicant laboratory to give confidence in the quality of its services, the physical facilities, i.e. the environment and the calibration/test equipment of the laboratory including maintenance and calibration having regard to the volume of work undertaken;

C) proficiency testing or other interlaboratory comparison performed by the applicant laboratory, the results of this proficiency testing, and the use of these results by the laboratory;

D) the actions taken to correct any non-compliances identified at previous assessments.

(e) Decision on accreditation

(1) The decision whether or not to accredit a laboratory shall be taken by an approved/recognized accreditation body on the basis of the information gathered during the accreditation process.

(2) An approved/recognized accreditation body shall not delegate its responsibility for granting, maintaining, extending, suspending or withdrawing accreditation.

(f) Granting accreditation

(1) An approved/recognized accreditation body shall transmit to each accredited laboratory formal accreditation documents such as a letter or a certificate signed by an officer who has been assigned such responsibility.

These formal accreditation documents shall permit identification of:

A) the name and address of the laboratory that has been accredited;
B) the scope of the accreditation including:

i) the tests or types of test for which accreditation has been granted;

ii) for tests, the materials or products tested, the methods used and the tests performed;

iii) for specific tests for which accreditation has been granted the methods used defined by written standards or reference documents that have been accepted by the accreditation body.

C) where appropriate, the persons recognized by the accreditation body as being responsible for the test certificates or the test reports;

D) the term of accreditation which shall be valid for a period not to exceed three years;

E) the accredited laboratory by a unique number.

(2) An approved/recognized accreditation body shall furnish notification to NIST required by Subpart B of this part.

(g) Surveillance and reassessment of accredited laboratories

(1) An approved/recognized accreditation body shall have an established documented program consistent with the accreditation granted for carrying out periodic surveillance and reassessment at sufficiently close intervals to ensure that its accredited laboratories continue to comply with accreditation requirements.

**The accreditation body shall conduct an appropriate form of surveillance evaluation of each participating laboratory at least once every six months.**

**The accreditation body shall perform a complete review and on-site assessment of each applicant laboratory at intervals not to exceed three years.**

(2) Surveillance and reassessment procedures shall be consistent with those concerning the assessment of laboratories as described in this Subpart.

(h) Proficiency Testing

(1) The approved/recognized accreditation body shall require each fastener testing laboratory it accredits, and each laboratory which has applied to it for accreditation to participate in proficiency testing comparable to that conducted under Subpart C by NVLAP.

**NIST evaluates all proficiency testing programs utilized by non-NVLAP participants, other than NVLAP, for acceptability under this program. (See Appendix D)**

(2) Although an accreditation shall not be granted or maintained only on the basis of the results of proficiency testing, accreditation shall not be granted or maintained if required proficiency testing participation is unsatisfactory.

(i) Certificates or reports issued by accredited laboratories

(1) An approved/recognized accreditation body shall normally allow an accredited laboratory to refer to its accreditation in test reports and test certificates that contain the results of tests or types of test for which accreditation is held.

(2) An approved/recognized accreditation body shall have a policy that defines the circumstances in which accredited laboratories are permitted to include in test reports or test certificates, the results of tests for which accreditation is not held and the results of sub-contracted tests.

Sec. 280.504 Relationship between approved/recognized accreditation body and laboratory

(a) An approved/recognized accreditation body shall have arrangements to ensure that the laboratory and its representatives afford such accommodation and co-operation as is necessary, to enable the accreditation body to verify compliance with the requirements for accreditation. These arrangements shall include provision for examination of documentation and access to all calibration and testing areas, records and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints.

(b) An approved/recognized accreditation body shall require that an accredited laboratory

(1) at all times complies with the relevant provisions of these regulations;

(2) claims that it is accredited only in respect of services for which it has been granted accreditation and which are carried out in accordance with these conditions;

(3) pays such fees as shall be determined by the accreditation body;

(4) does not use its accreditation in such a manner as to bring the accreditation body into disrepute and does not make any statement relevant to its accreditation which the accreditation body may consider misleading or unauthorized;

(5) upon suspension or withdrawal of its accreditation (however determined) forthwith discontinues its use of all advertising matter that contains any reference thereto and return any certificates of accreditation to the accreditation body;

(6) does not use its accreditation to state or imply any product approval by the accreditation body or any agency of the United States Government;

(7) endeavors to ensure that no certificate or report nor any part thereof is used in a misleading manner;

(8) in making reference to its accreditation status in communication media such as advertising, brochures or other documents, complies with the requirements of the accreditation body.

(c) Notification of change

(1) An approved/recognized accreditation body shall have arrangements to ensure that an accredited laboratory informs it without delay of changes in any aspect of the laboratory's status or operation that affects the laboratory's:

A) **Ownership**, legal, commercial or organizational status;

B) organization and management, e.g. key managerial staff;

C) policies or procedures, where appropriate;

D) **Location**, premises;

E) personnel, equipment, facilities, working environment or other resources, where significant;

F) authorized signatories;

or other such matters that may affect the laboratory's capability, or scope of accredited activities, or compliance with the requirements in this document or any other relevant criteria of competence specified by the accreditation body.

(2) Upon receipt of due notice of any intended changes relating to the requirements of this document, the relevant criteria of competence and any other requirements prescribed by the accreditation body, the accreditation body shall ensure that the laboratory carries out the necessary adjustments to its procedures within such time, as in the opinion of the body is reasonable. The laboratory shall notify the body when such adjustments are made.

(d) Directory of accredited laboratories

An approved/recognized accreditation body shall produce periodically a directory of accredited laboratories describing the

accreditation granted.

**The body shall produce a directory at least annually, with updates as required.**

## 8.0 LABORATORY REQUIREMENTS

Laboratories shall conform to all general and specific requirements imposed by the accreditation body. Laboratories shall be assessed against requirements consistent with subpart C of the regulations. ISO guide 25 shall be considered consistent with the general requirements of subpart C.

### 8.1 Test Methods

Laboratories may be accredited to perform any test method included in a fastener or fastener material specification covered under the Act. Each test method must be fully documented and suitable to be evaluated for accreditation.

### 8.2 Proficiency Testing

All laboratories shall participate in proficiency testing and obtain satisfactory results. Failure of a laboratory to obtain satisfactory results shall be cause for suspension or termination of accreditation.

Each laboratory shall be required to participate in a proficiency testing program designed to address the specific technical areas or types of test methods (not necessarily each test method) for which it has been accredited, at least once every six months.

Proficiency testing may be operated by NVLAP, or other competent provider deemed acceptable by NIST. Any proficiency test program utilized must be comparable in rigor and technical merit to the NVLAP fastener proficiency test program. **(See appendix D - Proficiency Test Providers)**

### 8.3 Test Reports

Any test reports issued by accredited laboratories which are to be covered under The Act shall conform to the reporting requirements of Section 280.6 of the regulations.

Sec. 280.6 Laboratory Test Reports

(a) When performing tests for which they are accredited under this part, each laboratory accredited under Subparts C, D, or E of these regulations and currently listed in the Accredited Laboratory List shall issue test reports of its work which accurately, clearly, and unambiguously present the test conditions, test set-up, test results, and all required information. All reports must be in

English or be translated into English, must be signed by an approved signatory, must employ a tamper resistant system, and contain the following information:

(1) Name and address of the laboratory;

(2) Unique identification of the test report including date of issue and serial number, or other appropriate means;

(3) Name and address of client;

(4) Fastener description, including:

(i) Manufacturer (name and address);

(ii) Product family (screw, nut, bolt, washer or stud), drive and/or head configuration as applicable;

(iii) Head markings (describe or draw manufacturer's recorded insignia and grade identification or property class symbols);

(iv) Nominal dimensions (diameter; length of bolt, screw or stud; thickness of load bearing washer or nut); thread form and class of fit;

(v) Product specification related to the laboratory in writing by the manufacturer, importer or distributor;

(vi) Lot identification number and other numbers as appropriate;

(vii) Specification and grade of material;

(viii) Coating material, thickness, process applied, baking if any, and corrosion resistance testing, if applicable;

(5) Sampling information

(i) Standard or reference for sampling scheme;

(ii) Production lot size and the number sampled and tested;

(iii) Name and affiliation of the person performing the lot sampling;

(6) Test Results

(i) Actual tests required by specification;

(ii) Test results for each sample;

(iii) All deviations from the test method;

(iv) All other items required on test reports according to the test method;

(v) Where the report contains results of tests performed by sub-contractors, these results shall be clearly identified along with the name of the laboratory and accreditation information listed in paragraph 10 of this section;

(vi) A statement that the samples tested either conform or do not conform to the fastener specifications or standards and explanation of any nonconformance;

(7) A statement that the report must not be reproduced except in full;

(8) A statement to the effect that the test report relates only to the item(s) tested;

(9) Name, title and signature of approved signatory accepting technical responsibility for the tests and test report;

(10) The name of the body which accredited the laboratory for the specific tests performed which are the subject of the report, and code number assigned to the laboratory by the accreditation body, and the expiration of accreditation.

(b) The laboratory shall issue corrections or additions to a test report only by a further document suitably marked, e.g. "supplement to test report serial number...". This document must specify which test result is in question, the content of the result, the explanation of the result, and the reason for the acceptance of the result.

8.4 Subcontracting By Laboratories

If an accredited laboratory subcontracts any work, the subcontractor shall conform to sec. 280.9 of the regulations.

Sec. 280.9 Subcontracting of Testing

(a) Whenever a laboratory accredited under Subparts C, D, or E of this part issues a test report under the Act and this part, it is implied that the report reflects work performed, and results obtained, by the personnel, equipment, and procedures of that laboratory. However, in some cases a laboratory may require the use of another facility due to equipment failure, need for specialized equipment, work overload, or to perform tests outside the laboratory's own scope of accreditation.

(b) Whenever a laboratory accredited under Subparts C, D, or E of this part subcontracts to another laboratory the performance of any test or portion of a test it must:

(1) Place the work with another laboratory accredited under either Subpart C, D, or E of this part;

(2) Clearly identify in its records, and in the report to the client, specifically which test method(s) or portions of a test method(s) were performed by the accredited laboratory and which were performed by the subcontractor; and,

(3) Inform the client, before the fact, that subcontracting will be necessary.

Subcontracting includes full or partial performance of a test method, sample preparation, sample conditioning or any activity which can affect the outcome of a test.

8.5 Recordkeeping

Accredited laboratories shall maintain records as required by sec. 280.7 of the regulations.

Sec. 280.7 Recordkeeping Requirements

(a) Each laboratory accredited under Subparts C, D, or E of this part shall retain for 10 years after the performance of a test all records pertaining to that test concerning the inspection and testing, and certification, of fasteners under the Act and these regulations. The final test report or the test records maintained by the laboratory shall contain sufficient information to permit the test to be repeated at a later time if a retest is necessary. The laboratory shall maintain the test report and a record of all original observations, calculations, and derived data.

The records shall include the identity of personnel involved in sample preparation and testing. All records shall be safely stored and held secure. Procedures for storage and retrieval of records must be documented and maintained in the laboratory's quality manual. Appropriate storage media, including paper, magnetic, optical, electronic, or microform, shall be used for records, such that the provisions of this section may be met.

8.6 Ownership of Laboratories by Manufacturers

NIST may at its option ban certain manufacturers from issuing test reports which comply with the Act. If this happens, all accreditation bodies and all affected laboratories will be notified.

Sec. 280.8 Ownership of Laboratories by Manufacturers

(a) If the Director (NIST) finds that, as to a specific type of fastener, and as to a specific type of inspection or testing, a ban on manufacturer ownership or affiliation with a laboratory performing tests under the Act and these regulations would increase the protection of health and safety of the public or industrial workers, the Director may impose such a ban.

(b) Before imposing a ban under paragraph (a) of this section, the Director shall provide advance notice and the opportunity for public comment.

# Appendices

APPENDICES

A - Change of Management, Ownership, or Location of an Approved/recognized Accreditation Program
B - Requirements for Foreign Laboratories and Accreditation Bodies
C - Status of Accredited Laboratories
D - Proficiency Testing Providers
E - References

APPENDIX A

CHANGE OF MANAGEMENT, OWNERSHIP OR LOCATION OF AN APPROVED/RECOGNIZED FASTENER ACCREDITATION PROGRAM

**Situation:** An accreditation body operating a NIST approved/recognized fastener testing laboratory accreditation program undergoes a significant change in management direction, a change in ownership, a change in the make up of a governing board, or other major change.

Any expenses incurred by NIST in resolving the status of an accreditation body shall be reimbursed by the organization requiring evaluation.

**Policy: Sale of organization**

NIST approval is not directly transferable upon the sale of an organization. Approval is automatically suspended on the date of sale unless prior arrangements have been concluded with NIST. NIST evaluates the new circumstances for conformance with the requirements; a site visit may be necessary.

Approval may be transferred upon payment of any required fees if the evaluation of the new ownership, management, staffing, or technical ability indicates conformance with the NIST requirements. The organization will normally receive a surveillance visit within 6 months after the transfer.

If the evaluation reveals significant changes that cause non-conformance with the NIST requirements, approval is suspended and will not be transferred until NIST is satisfied that the organization meets all requirements.

If approval is terminated by NIST, the new organization may apply for recognition when it believes that all criteria can be met.

CHANGE OF MANAGEMENT, OWNERSHIP OR LOCATION OF AN APPROVED/RECOGNIZED FASTENER ACCREDITATION PROGRAM

**Policy: Change in Management, Key Personnel**

When changes in management or key personnel occur and the ownership does not change, NIST approval/recognition may be suspended as of the date of implementation of the change pending NIST evaluation of the new circumstances; a site visit may be necessary. If sufficient notice is provided to NIST, evaluation may be performed with no lapse in approval/recognition.

Approval/recognition will be reinstated upon payment of any required fees after NIST determines that the change(s) do not significantly affect the operations of the organization. NIST will usually perform a surveillance visit within 6 months.

If NIST determines that the change significantly affects the operations of the organization, approval will not be reinstated until NIST is satisfied that the organization meets all requirements. If approval is terminated by NIST, the new organization may apply for recognition when that it believes that all criteria can be met.

**Policy: Change in Location**

If an organization changes the physical location of its premises, NIST may suspend approval/recognition pending evaluation of the effect of the change. NIST evaluates the new circumstances for conformance with the requirements; a site visit may be necessary.

Approval/recognition will be reinstated upon payment of any required fees if NIST determines that the operations of the organization conform to all requirements. NIST will usually perform a surveillance visit within 6 months.

CHANGE OF MANAGEMENT, OWNERSHIP OR LOCATION OF AN APPROVED/RECOGNIZED FASTENER ACCREDITATION PROGRAM

**Policy: Notification of Changes**

A Fastener Accreditation Program shall notify NIST no later than 10 days after significant changes to its operations, management, staffing, or technical abilities. Preferably, the notification should be well in advance of the changes to allow for a smooth transition.

If notification is not made within the 10 day limit, NIST will suspend approval/recognition upon obtaining knowledge of such changes and may begin termination procedures.

APPENDIX B

REQUIREMENTS FOR FOREIGN LABORATORIES AND ACCREDITATION BODIES

TO MEET THE U.S. FASTENER QUALITY ACT - P.L. 101-592

Listing of Foreign Testing Laboratories

Foreign testing laboratories whether located within or outside the United States, that desire to issue legally acceptable test reports concerning fasteners covered by the U.S. Fastener Quality Act - P.L. 101-592 (FQA, the Act) must meet all applicable conditions of the Act and be listed on the NIST - Accredited Laboratory List.

The basic requirement for listing is that a laboratory must be accredited. A foreign laboratory has several options: it may be accredited by (1) NVLAP, (2) a NIST-approved U.S. or foreign private accreditation body, or (3) a NIST-recognized foreign governmental accreditation body.

A laboratory's name may be placed on the NIST - Accredited Laboratory List only if a NIST-approved or recognized accreditation body supplies evidence of accreditation and pays a listing fee.

In order to maintain a listing, a laboratory must maintain its accredited status with a NIST-recognized or approved accreditation body and must continue to satisfy all applicable requirements of the regulations. The laboratory must also participate successfully in NIST recognized proficiency testing, and must agree to grant NIST the right to perform surveillance visits.

It is the responsibility of the accreditation body to keep NIST informed of the accreditation status of all laboratories in the program and any changes which may occur in that status within 10 days of such change. Changes such as renewal, suspension, revocation, or termination of accreditation, as well as changes in the scope of accreditation, in management or of other significant personnel must be reported. Failure to keep NIST appropriately informed may result in loss of approval or recognition, delisting, and possible assessment of civil penalties.

Recognition of Foreign Laboratory Accreditation Bodies

Foreign laboratory accreditation bodies shall meet the requirements of The Act in the same manner as domestic bodies. In general, there are two types of accreditation bodies, government operated and privately operated, as defined below.

Before granting recognition to a foreign accreditation body, NIST must be assured that the evaluation and accreditation of a laboratory by that body is performed with the degree of rigor and technical merit comparable to the requirements described in subpart C of the regulations.

Foreign Government Bodies

A foreign government accreditation body is here defined as:

> a body operated directly by a government agency and staffed with government personnel, or a body which has a formal arrangement recognizing the body as an official accreditation body acting on behalf of a government.

In order for NIST to have a reasonable degree of confidence in a foreign government accreditation body, NIST must perform some form of evaluation of the body prior to establishing a recognition agreement with the host government.

It is incumbent upon a foreign government accreditation body to contact NIST directly and request that a recognition agreement be considered. With the body's concurrence, arrangements are made for NIST to audit the body or to select other arrangements to determine comparability to section C and F of the regulations. An audit consists of one or more NIST staff visiting the accreditation body's facilities and observing its operations to determine if the body operates an acceptable program.

If an accreditation body does not agree to a NIST audit or other acceptable arrangement to determine comparability, NIST cannot recognize the body. Any laboratory in that country which desires to be on the Accredited Laboratory List will have to obtain accreditation from NVLAP or another NIST recognized or approved accreditation body.

If an accreditation body is determined to be acceptable, NIST establishes a recognition agreement stating that NIST will recognize an accreditation from that body as being comparable to Subpart C of the regulations. To keep the recognition in effect NIST audits will be performed at two year intervals.

Should NIST subsequently determine that it can no longer continue to recognize an accreditation body, NIST will inform all laboratories currently listed as being accredited by that body of their need to acquire accreditation from another NIST approved or recognized body in order to maintain their listing.

Foreign Private Accreditation Bodies

A foreign private accreditation body is defined here as:

> an accreditation body operated by a private entity, as either a for-profit, or not-for-profit business, which is not operated by or on behalf of a government.

NIST accepts requests for approval from foreign private accreditation bodies following the same procedures as used for domestic private accreditation bodies. Request forms and fee schedules may be obtained from:

> Administrator - FQA Accreditation Body Evaluation Program
> NIST
> Admin A629
> Gaithersburg, MD 20899

## APPENDIX C

### Status of Accredited Laboratories

Laboratories that have been duly accredited by NVLAP or a NIST recognized accreditation body and are included on the Accredited Laboratory List are entitled to cite that they are eligible to perform testing in compliance with The Act. The laboratory may issue test reports covering products or materials that are covered under the accreditation.

### Status of Laboratories When Recognition of an Accreditation Program is Terminated

If NIST recognition of an accreditation program is terminated, all laboratories currently accredited by that program will be advised that NIST may, at its discretion, remove them from the Accredited Laboratory List as of the date of the termination, and that they should expeditiously seek accreditation from NVLAP or another NIST recognized accreditation program.

NIST does not normally immediately suspend or remove laboratories from the Approved Laboratory List, unless they significantly contributed to the conditions which led to the accrediting organization's loss of recognition, or in NIST's judgement such adverse action is otherwise justified.

Laboratories that have previously been accredited by a body whose recognition has been terminated by NIST will normally be alllowed a specified period of time in which to acquire accreditation under NVLAP or another NIST-recognized accreditation program.

# APPENDIX D

## Proficiency Testing Providers

An accreditation body may conduct its own proficiency testing (PT) program or arrange for its laboratories to participate in a proficiency testing program operated by NVLAP or by another provider. However, laboratories that are similarly accredited by an accreditation body shall participate in the same round of identical proficiency testing conducted by the same provider.

All proficiency testing services, whether provided by the accreditation body or by others, shall be consistent in technical merit and rigor as that provided by NVLAP. An accreditation body must be able to demonstrate to NIST that the utilized proficiency test provider for a specified testing area can provide acceptable testing services, and that the provider is monitored continuously for acceptable performance.

An accreditation body must be able to demonstrate or substantiate that the proficiency test provider and test program for each applicable test area have the factors shown below at a sufficiently high level to satisfy NIST's requirements:

Provider

- Experience in PT operation
- Ethics and avoidance of conflict of interest
- Depth of technical knowledge, resources
- Quality system
- Appeal mechanism
- Recordkeeping procedures

Fastener Test Program

- Coverage of types of tests offered
- Capability of conducted test to measure lab competence adequately in area of interest
- Coverage of required technical fields

Sampling plans and types of test specimens utilized

System to certify test specimen characteristics

Specimen distribution, control procedures and packaging

Clarity and adequacy of instructions to participants

Ability of system to detect cheating and to control testing by labs

Frequency of required testing

Rigor of testing regimen

Method of grading test results and validity of statistical methods

Other

Records of surveillance of the provider by the accrediting body.

Investigation/resolution of complaints about the test provider

## Appendix E - REFERENCES

| | |
|---|---|
| ISO/IEC Guide 2 - 1991 | General terms and their definitions concerning standardization and related services. |
| ISO/IEC Guide 25 - 1990 | General requirements for the competence of calibration and testing laboratories. |
| ISO/IEC Guide 58 - 1993 | Calibration and Testing laboratory accreditation systems - General requirements for Operation and Recognition. |
| ISO 9000 Series | Quality Management and quality assurance standards |
| ISO 9004 - 1987 | Quality management and quality system elements - Guidelines. |
| ISO 9004-2 - 1987 | Quality management and quality system elements - Guidelines for Services. |

NVLAP Fastener Laboratory Accreditation Program Handbook
Available from: NIST/NVLAP, Bldg. 411, Gaithersburg, MD 20899
(301) 975-4016 FAX: (301) 926-2884

All document referenced as ISO/IEC are joint publications of the International Organization for Standardization and the International Electrotechnical Commission.